REMARKS

The present Reply is in response to the Final Office Action dated October 18, 2004 and the advisory action, dated March 1, 2005. As the "Reply Under 37 CFR §1.116 to Examiner's Action dated October 18, 2004" dated January 18, 2005 was not entered, applicant has re-submitted the amendments and arguments of the January 18, 2005 Reply.

Reconsideration of the allowability of the present application is requested respectfully.

Status of the Claims

Claims 35 to 46 were acted upon by the Examiner in the Office Action dated October 18, 2004. Claims 35, 39, 41 and 45 have been amended. No claims have been canceled. Claim 47 has been added. Accordingly, Claims 35 to 47 are presented for examination.

Support for Claim Amendments

Support for the amendment to Claim 35 is found on page 5, lines 1 to 7. Support for the amendment to Claim 41 is found on page 5, lines 8 to 12.

Support for the amendments to Claims 39 and 45 is found on page 5, lines 13 to 21, and in originally filed Claim 15, respectively.

Support for new claim 47 is found in originally filed claim 20.

ARGUMENTS

In response to the Examiner's Final Office Action dated October 18, 2004, and the advisory action, dated March 1, 2005, applicant respectfully traverses the Examiner's rejection of Claims 35 to 46.

The §112, First Paragraph, Rejections of Claims 35 and 41

The Examiner has rejected Claims 35 and 41 under 35 U.S.C. §112, first paragraph, as containing new subject matter and for failing to demonstrate that at the time of filing applicant was in possession of the presently claimed invention. In particular, the Examiner asserts that the specification lacks support for an "immune response to an antigen" as recited by Claims 35 and 41.

In response, Claims 35 and 41 have been amended to recite an "immune response" instead of an "immune response to an antigen". Claims 35 and 41 have been further amended to recite "microparticles comprising at least one antigen entrapped or encapsulated in biodegradable polymer". Support for the amendment to Claim 35 is found on page 5, lines 1 to 7. Support for the amendment to Claim 41 is found on page 5, lines 8 to 12.

In view of these amendments applicant respectfully requests that the rejection of Claims 35 and 41 under 35 U.S.C. §112, first paragraph, be withdrawn.

The §112, Second Paragraph, Rejections of Claims 35 to 46

The Examiner has rejected Claims 35 to 46, under 35 U.S.C. §112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the invention.

Claim 35 has been deemed vague for reciting an "immune response to an antigen" without the step of administering an antigen. In response, as noted above, Claim 35 has been amended to recite "A method of inducing a T_H1 polarized immune response comprising parenterally administering to a subject microparticles comprising at least one antigen entrapped or encapsulated in a biodegradable polymer, wherein said microparticles are sized such that the average diameter of said microparticles is from about 2.2 μm to about 4.3 μm." In view of this amendment applicant respectfully requests that the rejection of Claim 35, and those claims dependent thereon (Claims 36 to 40), under 35 U.S.C. §112, second paragraph, be withdrawn.

Claim 41 has been deemed vague for reciting a vaccine formulation for enhancing an "immune response to at least one antigen" without comprising "at least one antigen". In addition, for clarity, the Examiner has also suggested that Claim 41 be amended to recite "..microparticles, wherein said microparticles are sized...". In response, as noted above, Claim 41 has been amended to recite "A vaccine formulation for enhancing a T_H1 immune response and adapted for parenteral administration comprising a pharmaceutically acceptable carrier and a pharmaceutically effective amount of microparticles comprising at least one antigen entrapped or encapsulated in a biodegradable polymer, wherein said microparticles are sized such that the average diameter of said microparticles is from about 2.2 μm to about 4.3 μm". In view of these amendments applicant respectfully requests that the rejection of Claim 41, and those claims dependent thereon (Claims 42 to 46), under 35 U.S.C. §112,

second paragraph, be withdrawn.

The Examiner has asserted that Claim 37 has improper antecedent basis for the term "the biodegradable polymer" because Claim 35, from which Claim 37 depends, does not recite a "biodegradable polymer". Claim 35 has been amended to recite "a biodegradable polymer". In view of this amendment applicant respectfully requests that the rejection of Claim 37 under 35 U.S.C. §112, second paragraph, be withdrawn.

The Examiner has asserted that Claim 43 has improper antecedent basis for the term "the biodegradable polymer" because Claim 41, from which Claim 43 depends, does not recite "a biodegradable polymer". As noted above, Claim 41 has been amended to recite "a biodegradable polymer". In view of this amendment applicant respectfully requests that the rejection of Claim 43 under 35 U.S.C. §112, second paragraph, be withdrawn.

The Examiner has asserted that Claim 45 has improper antecedent basis for the term "the antigen" because Claim 41, from which Claim 45 depends, does not recite a "an antigen". Rather Claim 41 recites "at least one antigen". Claim 45 has been amended to recite "at least one antigen". In view of this amendment applicant respectfully requests that the rejection of Claim 45 under 35 U.S.C. §112, second paragraph, be withdrawn.

The Examiner has asserted that Claim 45 is indefinite for reciting a vaccine formulation comprising a *B. pertussis* antigen, while Claim 41, from which Claim 45 depends, recites a vaccine formulation lacking an antigen. Claim 41 has been amended to recite, "A vaccine formulation ...comprising a pharmaceutically acceptable carrier and a pharmaceutically effective amount of microparticles comprising at least one antigen entrapped or encapsulated in a biodegradable polymer...". Accordingly, presently amended Claim 41 now recites a vaccine formulation comprising "at least one antigen". In view of this amendment applicant respectfully requests that the rejection of Claim 45 under 35 U.S.C. §112, second paragraph, be withdrawn.

The Examiner has asserted that Claim 46 is indefinite for reciting a vaccine formulation with "...each subpopulation comprising a different antigen...", while Claim 41, from which Claim 46 depends, recites a vaccine formulation lacking an antigen. Claim 41 has been amended to recite, "A vaccine formulation ...comprising a pharmaceutically acceptable carrier and a pharmaceutically effective amount of microparticles comprising at least one antigen entrapped or encapsulated in a biodegradable polymer...". Accordingly,

presently amended Claim 41 now recites a vaccine formulation comprising "at least one antigen". In view of this amendment applicant respectfully requests that the rejection of Claim 46 under 35 U.S.C. §112, second paragraph, be withdrawn.

In the Advisory Action, dated March 1, 2005, the Examiner has asserted that the proposed amendments to Claim 41 create 35 U.S.C. §112, second paragraph, issues with regard to Claim 46. In particular, the Examiner has asserted that "the limitations 'antigen'and 'a biodegradable polymer' in claim 46 improperly broaden the scope" of the invention.

In response, applicant has amended claim 46 and has also included new claim 47, which is similar to claim 46 but written in independent form.

The Examiner has asserted that the phrase "different antigen entrapped or encapsulated by a biodegradable polymer" of Claim 46 raises issues under 35 U.S.C. §112, second paragraph.

In response, applicant has amended Claim 46 to recite:

> The vaccine formulation of Claim 41, wherein said formulation comprises at least 2 subpopulations of microparticles, each subpopulation comprising a different antigen entrapped or encapsulated by a biodegradable polymer, wherein said microparticles are sized such that the average diameter of said ~~the~~ microparticles is from about 2.2 μm to about 4.3 μm.

Previously Claim 46 recited "wherein said microparticles comprise at least two subpopulations."

Claim 41, on which claim 46 depends, requires a formulation comprising microparticles comprising at least one antigen. Claim 46 requires a formulation comprising at least two subpopulations of microparticles, each comprising different antigens. As Claim 46 depends from Claim 41, the microparticles comprising at least one antigen of claim 41 are necessarily part of one of the formulation of Claim 46. Claim 46 requires the microparticle subpopulations to comprise different antigens. Therefore, the formulation of Claim 46 must include an antigen that is not the same antigen as recited in Claim 41.

Claim 46 has also been amended to include the size recitation of Claim 41, in order to further define the microparticles of the second subpopulation.

In regard to the phrase "a different antigen entrapped or encapsulated in a biodegradable polymer" of Claim 46 lacking clarity, applicant submits that the phrase, when taken as a whole, is not indefinite. The phrase needs no antecedent basis because it uses the

modifier "a" to introduce the claim element. Based on the claims it should be clear that: each antigen is entrapped or encapsulated in a biodegradable polymer; and the biodegradable polymers can be of the same chemical composition.

In addition, applicant has also added new claim 47, which is similar to claim 46 written in independent form.

A favorable action on the merits is requested respectfully.

Respectfully submitted,

Jonathan M. Dermott, Ph.D.
Registration No. 48,608

SYNNESTVEDT & LECHNER LLP
2600 Aramark Tower
1101 Market Street
Philadelphia, Pennsylvania 19107
(215) 923-4466

M:\JDermott\Merrion\26485-A USA\Reply to oa of 2004.10.18.rtf